DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 10, 2014

AmeriWater, Inc.
Mr. Brian R. Bowman
Quality & Regulatory Administrator
1303 Stanley Avenue
Dayton, OH 45404

Re: K141213
Trade/Device Name: AmeriWater Ozone Disinfection System
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: FIN
Dated: November 5, 2014
Received: November 10, 2014

Dear Mr. Bowman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

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Indications for Use

510(k) Number (if known): K141213

Device Name: AmeriWater Ozone Disinfection System

Indications For Use:

The AmeriWater Ozone Disinfection System is an optional accessory for the AmeriWater Bicarb Solution Mix and Distribution System (SDS) cleared for market under K051031 and the AmeriWater Water Purification System (WPS) for Hemodialysis cleared for market under K991519. It is intended for use in hospitals and dialysis clinics for the disinfection of the AmeriWater SDS and WPS system. The disinfection process is completed during off-hours when the SDS or WPS are not being used for patient treatment. The AmeriWater Ozone Disinfection System provides dissolved aqueous ozone concentrations of at least 0.5 ppm with a contact time of at least 30 minutes for disinfection of the WPS and SDS systems (the entire disinfection process takes approximately 2 hours to complete and longer contact times may be necessary based on microbial loads). The Ozone Disinfection System is designed to produce water with a microbial count of 50 CFU/ml or less.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(K) SUMMARY

December 8, 2014

Classification Name: Hemodialysis System and Accessories
Common/Usual Name: Ozone Generator/Ozone Generating System
Proprietary Name: AmeriWater Ozone Disinfection System
Classification: Class II Medical Device under 21 CFR §876.5820.
Panel: Gastroenterology
Product Code: FIN
510(k) Submitter: AmeriWater, Inc.
Establishment Registration Number: 1530185
Owner Operator Number: 9009428
Contact Person: Brian Bowman, Quality and Regulatory Administrator
Phone: (937) 461-8833, Fax: (937) 461-1988, Email: brianbowman@ameriwater.com
Predicate Device: $TANGO_3$ Water Storage Tank with Ozone Disinfection System (K093641)

Intended Use: The AmeriWater Ozone Disinfection System is an optional accessory for the AmeriWater Bicarb Solution Mix and Distribution System (SDS) cleared for market under K051031 and the AmeriWater Water Purification System (WPS) for Hemodialysis cleared for market under K991519. It is intended for use in hospitals and dialysis clinics for the disinfection of the AmeriWater SDS and WPS system. The disinfection process is completed during off-hours when the SDS or WPS are not being used for patient treatment. The AmeriWater Ozone Disinfection System provides dissolved aqueous ozone concentrations of at least 0.5 ppm with a contact time of at least 30 minutes for disinfection of the WPS and SDS systems (the entire disinfection process takes approximately 2 hours to complete and longer contact times may be necessary based on microbial loads). The Ozone Disinfection System is designed to produce water with a microbial count of 50 CFU/ml or less.

Device Description: The AmeriWater Ozone Disinfection System is a compact portable device that connects to the AmeriWater Bicarb Solution Mix and Distribution System (SDS) and the AmeriWater Water Purification System (WPS) for Hemodialysis for disinfection of the systems. Microbial reduction is achieved by a combination of disinfection by ozone and by physical removal by draining, flushing, and refilling the system being disinfected with fresh water. The Heatsan system has been designed to be in compliance with the requirements of ANSI/AAMI/ISO 13959:2009 Water for hemodialysis and related therapies and ANSI/AAMI/ISO 26722:2009 Water treatment equipment for hemodialysis applications and related therapies.

The AmeriWater Ozone Disinfection System uses a high technology corona discharge process for producing ozone. Ozone is manufactured by drawing oxygen (O_2) into the ozone generator and exposing it to multiple high voltage electrical discharges. This causes a percentage of the oxygen molecules to dissociate and reassemble as ozone (O_3). The ozone is drawn into the water by a venturi injector / mixer allowing the ozone to be injected into the water under a vacuum condition. The AmeriWater Ozone Disinfection System is a complete unit with ozone generator, venturi injector mixer, gas off chamber with excess ozone gas destruct, feed water flow meter, oxygen flow meter, and vacuum gauge.

The driving force of the AmeriWater Ozone Disinfection System is the distribution pump on the WPS water loop and the mix and distribution pumps on the SDS. A valve arrangement installed on the outlet of the WPS distribution pump and the SDS pumps allow for the diversion of purified water flow into the AmeriWater Ozone Disinfection System and back into the SDS or WPS storage tanks. The pumps force the purified water from the WPS storage tank into the Ozone Disinfection System, which enriches it with ozone and returns it to the WPS storage tank. Likewise, the purified water from the SDS mix and distribution tanks is pumped into the Ozone Disinfection System where it is enriched with ozone and returned to the tanks. When the water flow has been adjusted properly, a vacuum will draw oxygen (from

a medical grade oxygen source) into the ozone generator and ozone will be created. The ozone generator has a vacuum switch and will not operate without an adequate vacuum from the venturi injector as indicated on the Ozone Disinfection System vacuum gauge.

The purified water from the WPS or SDS flows into the Ozone system through the feed flow meter and into a venturi injector creating a vacuum that draws the oxygen through the generator creating ozone in concentrations greater than 0.5 ppm. The ozone is then mixed in the water flow. The ozone rich water enters the gas off tank to remove any excess, un-dissolved ozone gas. The water-ozone mixture enters and exits at the bottom of the gas off tank. The excess (un-dissolved) ozone will slowly displace the water in the tank and is vented at the top of the tank. The excess ozone gas then enters the ozone destruct chamber where it is destroyed while the ozone-rich water is directed back to the system being disinfected. Ozone concentrations are monitored using RPC Ozone Test strips, cleared for market under K132344.

The intended disinfection endpoint for the AmeriWater Ozone Disinfection System with the AmeriWater Water Disinfection System (WPS) and the AmeriWater Solution Distribution System (SDS) following disinfection and rinse is a total bacterial count less than or equal to 50 CFU/mL; when the system being disinfected is properly maintained (with bacterial counts $\leq$ 100 CFU/mL; and endotoxin $\leq$ 0.25 EU/mL). In the event that the system being disinfected has not been properly maintained, additional contact time or additional disinfection cycles may be required to achieve the desired end point. ANSI/AAMI/ISO 13959:2009 requires that monitoring of the water storage tanks for bacteria and endotoxin levels is accomplished indirectly by monitoring the water at the first outlet to the distribution loop. Water distribution systems are monitored by taking samples of the water at the first and last outlets of the water distribution loop. ANSI/AAMI/ISO 26722:2009 specifies that an ozone level of 0.5 ppm, sustained for at least 10 minutes, is considered necessary to kill bacterial organisms. AmeriWater recommends an ozone level of 0.5 ppm or greater for disinfection with a contact time of at least 30 minutes. The AmeriWater disinfection process takes approximately 2 hours to complete using the Ozone Disinfection System. This includes the time to build the ozone concentration in the storage tank and loop, as well as contact times.

Summary of Performance Testing: Non-clinical testing was conducted to verify and validate the efficacy of the system in the reduction of bacteria in the AmeriWater Bicarb Solution Mix and Distribution System (SDS) and the AmeriWater Water Purification System (WPS) for Hemodialysis. Testing was conducted under worse case conditions (minimum recommended concentration and contact time) using a microbial challenge solution containing a range of test organisms that represents the waterborne bacteria found in hemodialysis water systems. The species included were Pseudomonas aeruginosa (Gram-negative bacterium), Staphylococcus aureus (Gram-positive bacterium), Candida albicans (yeast), Asperigillus fumigatus (mold), and Mycobacterium fortuitum (non tuberculosis mycobacterium). Test runs with the WPS were conducted with a 48-hour incubation time, a 30-day incubation time (based on the recommended disinfection frequency), and simulated use testing. The SDS testing included test runs with a 48-hour incubation time, 6-day incubation time (based on the recommended disinfection frequency), and simulated use testing. The 48-hour, 6-day, and 30-day incubation tests were designed to demonstrate a 6 log reduction in bacteria, yeast and mold levels, and a 3 log reduction in non tuberculosis mycobacteria. Simulated use testing was conducted to show evidence that the specified endpoints were achieved during normal operation of the Ozone Disinfection system with the WPS and SDS systems. The results of microbiological testing demonstrated a 6 log reduction in bacteria, yeast and mold levels, and a 3 log reduction in non tuberculosis mycobacteria; and the desired microbial endpoint. The results were achieved by a combination of disinfection by ozone and by physical removal by draining, flushing, and refilling the system being disinfected with fresh water.

Non-clinical virucidal efficacy testing was also conducted to evaluate the ability of the AmeriWater Ozone Disinfection System (ODS) to reduce viruses in water. Testing was conducted under worse case conditions (minimum recommended concentration and contact time). The Herpes simplex virus type 1 and Poliovirus type 1 were used in the virucidal efficacy testing. Under the conditions of this investigation, the AmeriWater Ozone Disinfection System demonstrated complete inactivation of the viruses used in the test.

Biocompatibility testing was conducted to determine if extended exposure of the components of the AmeriWater Ozone Disinfection system (ODS) in conjunction with the AmeriWater Water Purification System (WPS) and the AmeriWater Bicarb Solution Mix and Distribution System (SDS) to aqueous ozone results in leaching, and to demonstrate the absence of toxic leachables. These tests were designed to expose the Ozone Disinfection System in conjunction with the AmeriWater WPS and SDS, when operating the system at the highest ozone level produced when operating the system per the instructions for use for the device, for the expected operating life of the device. There were no significant increases in any of the toxins identified in the AAMI standards, and levels for the toxins did not reach or exceed the AAMI suggested maximum levels. Total organic carbon levels actually decreased during the duration of the test. There were no visible signs of material degradation in the WPS, SDS, or ODS systems. Residual ozone levels were reduced to <0.1 ppm following disinfection in both the WPS and SDS systems. Ambient air ozone levels remained below the permissible exposure limit per OSHA 29CFR and the permissible exposure limit indicated in FDA 21CRFR during use of the AmeriWater Ozone Disinfection System in conjunction with the AmeriWater WPS and SDS systems.

The AmeriWater Ozone Disifnection System has been third-party tested and listed to UL 979. The UL 979 standard is the UL standard for Water Treatment Appliances. The scope of the standard includes requirements covering electrically operated water treatment appliances for household and commercial use. These requirements cover appliances utilizing features that treat water through the use of cation exchange water softeners, ionization, filters, ultraviolet radiation, ozone generation, and reverse osmosis. Testing performed on the device to show evidence of product safety. These tests include starting current test, power input test, leakage current test, leakage current after humidity, resistance to grounding, temperature test, dielectric voltage withstand test, abnormal operation test, strain relief test, push back relief test, operational test, stability test, humidity conditioning, insulation resistance, and thermal endurance test.

UL 979 provides specific requirements for device construction, including requirements for frames and enclosures, accessibility of uninsulated live parts, protection against corrosion, exposure to water, mechanical assembly, supply connections for cord connected appliances, grounding, live parts, electrical insulation, internal and external wiring connections, separation of circuits, spacings (low-voltage and isolated limited-energy circuits, and high-voltage circuits), capacitors, switches and controls, transformers and power supplies, seals gaskets and diaphragms, motors, ratings, device markings, and installation instructions. These requirements are intended to ensure safe operation of an appliance when used in a home or commercial environment. AmeriWater has incorporated several safety features into the device design to protect the operator of the device. The unit is sealed by several fasteners that require a tool to open and access the inside of the device. UL 979 – compliant internal electrical wiring, wiring insulation, and wiring routed away from sharp edges. A user is protected by a sealed unit not exposing them to any electrical hazards, when the access panel is removed there is a door switch that kills power to the unit.

Test results from non-clinical testing, biocompatibility testing, and electrical safety testing indicate that the device is as safe and effective for its intended purpose as the predicate device.

Statement of Substantial Equivalence: The AmeriWater Ozone Disinfection System is substantially equivalent in intended use, function, and technology to the $TANGO_3$ Water Storage Tank with Ozone Disinfection System (K093641) marketed by $TANGO_3$ LLC. It is also similar in intended use, function, and technology to the GE Infrastructure, Water & Process Technologies' O_3Z Ozone System (K043207). The table on the following page, along with the documentation included in this submission, demonstrates that there are no new issues of safety or effectiveness, and that the AmeriWater Ozone Disinfection System is as safe and effective for its intended purpose as the predicate device.

AmeriWater Ozone Disinfection System	$TANGO_3$ Ozone Disinfection System	GE O_3Z Ozone Sanitizing System
Intended Use: Disinfection of AmeriWater Solution Mix and Distribution System (SDS) and AmeriWater Water Purification System for Dialysis (WPS) storage tank and distribution loop.	Intended Use: Disinfection of the water distribution system of a dialysis facility	Intended Use: Disinfection and decalcification of the bicarbonate portion of the GE Solution Delivery System (SDS).
Water is pumped through a venturi injector to create vacuum. The vacuum pulls oxygen through the ozone generator resulting in ozone production.	Water is pumped through a venturi injector to create vacuum. The vacuum pulls air through the ozone generator resulting in ozone production.	Water is pumped through a venturi injector to create vacuum. The vacuum pulls air through the ozone generator resulting in ozone production.
Water is pumped into the ozone system by an external pump.	Water is pumped into the ozone system by an external pump ($TANGO_3$ Recirc Pump).	Water is pumped into the ozone system by an external pump (the GE SDS system pumps).
The ozone generator uses a corona discharge to create ozone.	The ozone generator uses a corona discharge to create ozone.	The ozone generator uses a corona discharge to create ozone.
Electrical requirements: 115 VAC, 60 Hz, 15 Amps, 1 Ph	Electrical requirements: 208 VAC 3 PH or 240 VAC 1 PH, 60Hz, 25 Amp (pumps) 120 VAC, 60 Hz (control)	Electrical requirements: 115 VAC, 60 Hz, 3 Amps, 1 Phase.
Portable device Complete system enclosed in a cabinet with handle and casters.	Not portable Ozone disinfection system is part of water storage tank.	Not portable Wall-mounted in fixed location.
Uses medical grade oxygen to produce ozone.	Uses ambient air for ozone production.	Uses ambient air for ozone production.
Manual Disinfection Process	Automated Disinfection Process Software (PLC) controlled	Manual Disinfection Process
Ozone concentration monitored with 510K cleared test strips.	Ozone concentration monitored with inline ozone monitor.	Ozone concentration monitored with digital Hach chlorine colorimeter with Total Chlorine DPD test pillows.